UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IMPAX LABORATORIES, INC., *Plaintiff*, v. ACTAVIS LABORATORIES FL, INC., and ACTAVIS PHARMA INC., *Defendants*.	Civil Action No. 15-6934 (SRC-CLW) Oral Argument Requested *Electronically Filed*

ACTAVIS LABORATORIES FL, INC. AND ACTAVIS PHARMA INC.'S MEMORANDUM IN OPPOSITION TO IMPAX'S MOTION TO STAY PROCEEDINGS WITH RESPECT TO U.S. PATENT NO. 7,094,427

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Defendants Actavis Laboratories FL, Inc. and Actavis Pharma Inc. (collectively "Actavis") respectfully ask the Court to deny Impax's motion to stay all activities in this case with respect to the '427 patent, one of the six patents in suit in this ANDA suit, pending completion of the ongoing *ex parte* reexamination of that patent. As discussed below, to avoid unfair prejudice to Actavis, Impax should be required to serve its Local Patent Rule 3.1, 3.4A & 3.6 infringement and validity contentions for the '427 patent as previously scheduled, and Actavis should be allowed to proceed with fact discovery on certain matters relating to the '427 patent, including the history, conception, reduction to practice, use and/or sale of any embodiments or alleged inventions disclosed or claimed in the '427 patent, the support for the disclosures made in and inventions claimed in the '427 patent, and the information and factual materials (including affidavits) disclosed in the specification or used in the prosecution and reexamination history pertaining to the '427 patent and any related patents.

INTRODUCTION AND SUMMARY OF ARGUMENT

Impax concedes that it has "abandoned" the currently issued claims of the '427 patent, and that those claims are "certain" not to reemerge from the reexamination. Impax Br. (D.I. 43-1) at 1 (emphasis added). At best, all Impax can hope for is that the appeals process may result in overturning the PTO's current rejection of its proposed amended claims. Impax's proposed stay is thus a vehicle to try to keep the '427 patent alive as long as possible while the appeals process plays out, all based on amended claims that currently stand rejected. As discussed below, that appeals process, which could include Impax's current appeal to the Patent Trial and Appeal Board ("PTAB"), and potential appeals to the Federal Circuit and beyond, plus remand to

the PTO thereafter for issuance of a reexam certificate, could take years before it is completed.[1] At that time, if Impax's complete stay has been in place, there would have been ***no*** progress on the '427 case – in effect the '427 case would have to start all over again, essentially splitting this case into two and causing more delay.

Actavis would be unduly prejudiced by such a complete stay. Not only would the case have to start over from scratch if the '427 patent pops up with amended claims years from now, but litigating the case would likely extend well beyond both the completion of the case as to the other five patents and the expiration of the 30-month stay. Such an outcome would be, in effect, a *de facto* extension of the 30-month stay, likely further delaying a product launch by Actavis even if it wins on the other five patents, or else forcing Actavis to launch its ANDA products under risk of damages from an amended '427 patent. Clearly, if there is to be a delay in the litigation of the '427 patent, then because of the potential for further litigation on the patent, any stay should still enable the parties to carry out work that can be done efficiently now, so as to reduce the time needed for litigation later.

Second, it would also be unfair and prejudicial for Impax to obtain a complete stay now, just before it is required by the agreed-upon schedule to disclose its infringement and validity contentions for the '427 patent. Impax initially agreed to a full schedule for this case that did not provide for a stay. Under that schedule, Actavis has already provided its invalidity and non-infringement contentions for the '427 patent. But *Impax* now seeks a stay in part based on the desire to avoid having to disclose *its* infringement and validity contentions. *See, e.g.*, D.I. 43-1

[1] *See* Impax's Proposed Order. In its brief, Impax confusingly states that it seeks a stay "only until completion of the '427 reexamination proceedings at the PTO." D.I. 43-1 at 1. It seems Impax is seeking a stay that would extend through the present appeal to the Patent Trial and Appeal Board ("PTAB"), to a potential appeal to the Federal Circuit or even an effort to seek review by the Supreme Court, plus additional time for a remand to the PTO, until the issuance of the final reexamination certificate in the PTO.

at 1. As a result, a complete stay would leave Actavis with ***no*** disclosure of the basis for Actavis's allegations that Actavis's ANDA Products infringe the '427 patent, since Impax's complaint contained ***no*** facts supporting its infringement charge. Because the critical core limitations of the '427 claims remain unchanged in Impax's proposed amended claims (*see* Appendix A), it is certainly possible for Impax to disclose its infringement contentions and the factual basis for those contentions *today*, and such disclosure would in any event have to be made eventually if any new claims survive reexamination. Actavis would be significantly prejudiced if Impax is allowed to deprive Actavis for years of Impax's disclosures, only for Impax to reveal them if the lawsuit comes back to life.

Third, even if the '427 patent is stayed, Actavis will have to take fact discovery of Impax in order to defend itself with respect to the other five patents in suit. Those patents cover very similar subject matter to the '427 patent, which itself is prior art to the five patents, and the '427 patent also shares an inventor in common with the other five patents. Thus, as part of the ongoing case on the other five patents, there will be factual discovery concerning, *e.g.*, Impax's history of work in extended release formulations of Levodopa and Carbidopa, including its own work done on the prior art '427 patent. As a result, it makes sense to allow the parties now to proceed with fact discovery pertaining to the '427 patent, as such work can be accomplished efficiently in the context of the related discovery that will be proceeding in any event given the overlap with the other five patents. Specifically, Actavis should be allowed to proceed with fact discovery relating to the history, conception, reduction to practice, use and/or sale of any embodiments or alleged inventions disclosed or claimed in the '427 patent, the support for the disclosures made in and inventions claimed in the '427 patent, and the information and factual materials (including affidavits) disclosed in the specification or used in the prosecution and

reexamination history pertaining to the '427 patent and any related patents. Allowing such discovery also would reduce the work that would have to be done in the future, should Impax's amended claims spring into life after appeal. This would reduce the prejudice caused by the reexamination delay by hopefully shortening the time to final resolution of this case should the '427 claims emerge in amended form after the appeals process.

In short, there is no reason for a complete, one-sided stay order causing prejudice solely to Actavis. Instead, to allow the litigation to proceed fairly and efficiently, while recognizing that the '427 claims may never emerge from the reexamination process, Actavis asks this Court to (i) require Impax to proceed according to the existing, agreed-upon schedule and make its Local Patent Rule 3.1, 3.4A & 3.6 validity and infringement contentions as currently scheduled, so that the basis for its contentions are fully disclosed, and (ii) allow fact discovery to proceed with respect to the '427 patent, since that discovery would be required in the event Impax obtains its amended claims, and the discovery is also relevant to the other patents given the '427 patent's status as prior art. Allowing these activities to proceed would reduce the prejudice of a stay on Actavis.

Finally, Impax tries to paint this as a routine stay motion. It is anything but. When Impax brought suit on the issued '427 claims the reexamination was far along. Impax had already abandoned the issued '427 claims in the PTO, and was well aware that its amended claims had also been rejected by the PTO and were up on appeal to the PTAB. Thus, Impax clearly chose to sue Actavis for infringement of '427 patent claims that Impax *knew* could never be enforced. While Impax says it was "was left with no choice but to enforce its intellectual property rights by bringing suit or to tolerate Defendants' infringement of Plaintiff's intellectual property rights and allow a generic version of the innovative RYTARY® medicine on the

market," this is simply untrue. D.I. 43-1 at 4. By virtue of Impax's filing suit on the five *other* patents-in-suit, approval of Actavis's ANDA is subject to a 30-month stay of approval under 21 U.S.C. § 355(j)(5)(B)(iii), which means that Actavis cannot launch its products until February 5, 2018, or such time as the Court decides the case in Actavis's favor. Thus, Impax did not need to include the '427 patent in order to prevent imminent competition. Indeed, there was nothing to stop Impax from refraining from asserting the '427 patent until such time as the reexamination could be resolved.

Under the circumstances, it is both more efficient and fair if Impax is now required to serve its infringement and validity contentions as originally scheduled, and Actavis can proceed with fact discovery with respect to the '427 patent and the formulations described therein.

BACKGROUND FACTS

The '427 Patent: The '427 patent is entitled "Combination Immediate Release Controlled Release Levodopa/Carbidopa Dosage Forms. It issued on August 22, 2006, with 31 claims, of which Impax has asserted 20 against Actavis in this case. All claims depend from claim 1. Claim 1 – and all the other claims both as originally issued, plus as proposed on amendment – contain the following core language:

1. A pharmaceutical dosage form having an immediate release component and a controlled release component comprising:

> a) an immediate release component comprising a ratio of Carbidopa to Levodopa of from about 1: 1 to about 1: 50 such that the in vitro dissolution rate of the immediate release component according to measurements under the USP paddle method of 50 rpm in 900 ml aqueous buffer at pH 4 at 37° C. is from about 10% to about 99% Levodopa released after 15 minutes and from about 60% to about 99% after 1 hour; and
>
> b) a controlled release component comprising a ratio of Carbidopa to Levodopa of from about 1: 1 to about 1: 50 such that the in vitro dissolution rate of the controlled release component according to measurements under the USP paddle method of 50 rpm in 900 ml aqueous buffer at pH 4 at 37° C. is from about 10% to about 60% Levodopa released after 1 hour; from about 20% to about 80%

> Levodopa [rel]eased after 2 hours; and from about 30% to about 99% Levodopa released after about 6 hours, the in vitro release rate chosen such that the initial peak plasma level of Levodopa obtained in vivo occurs between 0.1 and 6 hours after administration of the dosage form to a patient.

See Appendix A for the full language of Claim 1 as initially issued and as amended.[2]

Like the other patents-in-suit, the '427 patent is assigned to Impax and reflects drug development work done at Impax. The '427 patent is prior art to the five other asserted patents, and all six patents-in-suit have a common inventor, Ann F. Hsu. All six of the patents-in-suit also relate to the same subject matter: dosage forms containing Levodopa and Carbidopa used for, *inter alia*, the treatment of Parkinson's disease. And, all the patents relate to dosage forms that have an immediate release and controlled release component containing Levodopa and Carbidopa.

The Reexamination: A request for *Ex Parte* Reexamination of the '427 claims was filed by a third party on June 15, 2012, citing multiple prior art references, including references identified as Chiesi, Schmidt, Licht and Rubin, and setting forth both obviousness and anticipation arguments against the claims. Re 90/0012293 (6/15/2012), *passim*. All four of these references had not been considered in the original prosecution. *Ex parte* reexaminations are handled by the Central Reexamination Unit of the PTO, using a three-examiner panel. The PTO granted the request for reexamination on July 25, 2012, finding that these references raised substantial new questions of patentability. *See* Decl. of Kenneth Mueller ("Mueller Decl."), ¶ 6. On May 3, 2013, the PTO issued an office action rejecting all 31 issued claims as anticipated or obvious based on the Licht and Rubin references. *Id.*, ¶ 7. In a response filed on November 4,

[2] *See* Appendix A hereto, comparing Claim 1 of the issued '427 patent, at D.I. 1-1, with proposed amended claim 1 in Impax's Appeal Brief to the PTAB. A copy of the proposed amended claims for the '427 patent on appeal is attached as Exhibit 2 to the Mueller Declaration.

2013, Impax amended or dropped all existing claims, added certain new claims, and submitted arguments against the PTO's rejections. *Id.*, ¶ 8. Impax also submitted declarations from the inventors, with exhibits. *Id.* After an oral interview with the three examiners, Impax again amended its claims on March 4, 2014. *Id.*, ¶ 10. This time, Impax's amendment to claim 1 – from which all other claims depended – added new substantive limitations not previously set forth in the claims. *Id.* Impax argued that these claims, as amended, should be allowed. *Id.*

On July 25, 2014, the PTO responded in detail to Impax's arguments and rejected all the claims (as amended) either as being anticipated by or rendered obvious over Licht and/or Rubin. This rejection was made final. Mueller Decl., ¶ 11. In response, on Sept. 25, 2014, Impax submitted another set of amendments, including further modifications to claim 1, from which all other claims depended. *Id.*, ¶ 12. Impax made 30 pages of arguments in support of these amended claims. After the PTO declined to enter certain proposed additional amendments suggested by Impax, Impax filed a Notice of Appeal on November 25, 2014, and a Brief on Appeal on January 26, 2015. Impax's brief acknowledges that the "claims on appeal" are "the amended claims submitted on December 29, 2014, and entered on January 15, 2015." *Id.*, ¶ 14. A copy of those amended claims on appeal is attached to the Mueller Decl. as Ex. 2. The PTO examiners submitted their responsive brief on March 23, 2015, maintaining and supporting their rejections on anticipation and obviousness grounds. *Id.*, ¶ 13. Impax submitted its Reply Brief on May 18, 2015, and requested an oral hearing. The oral hearing before the Patent Trial and Appeal Board ("PTAB") was recently scheduled for June 1, 2016.

In this motion to stay, Impax acknowledges that it "abandoned pursuit of the claims of the '427 Patent in their originally-issued form," and that it is "certain" that those originally issued claims will not "survive the reexamination proceeding." D.I. 43-1 at 2 (emphasis added).

It also acknowledges that no claims will survive the pending reexamination of the '427 patent unless Impax prevails on appeal either in the PTAB or in the Federal Circuit. *Id.* at 7.

Actavis's ANDA and Paragraph IV Notice Letters: On June 9, 2015, defendant Actavis Laboratories FL, Inc. submitted an ANDA to the FDA seeking approval to manufacture and sell generic versions of Impax's Rytary® (Levodopa/Carbidopa). Actavis Laboratories FL, Inc. also provided Paragraph IV Notice Letters to Impax in August 2015 indicating that it was seeking approval to engage in the commercial manufacture, use, or sale of those products before the expiration of the six patents in suit. One of those Notice Letters described Actavis's grounds for concluding that the '427 claims were invalid and/or not infringed.

Impax's Claims Against Actavis: Shortly thereafter, Impax filed its complaint against Actavis. The complaint made no mention of the pending reexamination, or of Impax's abandonment of the issued '427 claims during the reexamination. The complaint also failed to identify any specific '427 claim that was infringed. Actavis subsequently filed answers and counterclaims, denying liability.

The parties then negotiated and submitted to the Court an agreed-upon schedule that did not include any stay for the '427 patent. The schedule was approved. D.I. 33. Although the schedule does not set forth a specific trial date, the schedule was designed to provide for a trial in the Fall of 2017, in order to give room for a judgment from the court before the 30-month stay expires on February 5, 2018. Pursuant to this schedule, on Jan. 18, 2016, Impax provided Actavis with a list of all the claims in the '427 patent that it contended were being infringed by Actavis's ANDA Products, so as to identify the claims Actavis was required to address in its invalidity and non-infringement contentions. Most of the originally issued '427 claims were listed. Actavis proceeded to submit its invalidity and non-infringement contentions with respect

to those claims on March 10, 2016. Under the current schedule, Impax's disclosure of its infringement and validity contentions are due on June 3, 2016. D.I. 42.

To date, Impax has not articulated any factual support for its conclusory allegation that Actavis's ANDA products infringe any of the '427 claims. For example, it has never provided any evidence or explanation for its allegation that the Actavis ANDA products meet the limitations of Claim 1, quoted above. Other than the fact that the '427 patent is an Orange Book patent and that Actavis Laboratories FL, Inc. has filed an ANDA, Impax has disclosed *no* evidence demonstrating how Actavis's products infringe the '427 claims. *See* D.I. 27, Count I. And since all of Impax's proposed amended claims in the reexamination incorporate the language of the existing claims, plus adding a few new limitations, Impax has not actually disclosed any facts showing how Actavis's ANDA products would even infringe any of its proposed amended claims. Impax's proposed stay thus would deprive Actavis of the kind of mutual disclosure of contentions that is required under the New Jersey Rules.

LEGAL STANDARDS

The decision whether to stay a case pending the outcome of an ongoing reexamination proceeding is discretionary. *ELM, Inc. v. Venmill Industries, Inc.*, 2105 U.S. Dist. LEXUS 79234 *1 (D. N.J., June 18, 2015) (Chesler, J.). In deciding whether to stay a matter pending reexamination, courts typically use a three-part test. A court should consider "(1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether a stay will simplify the issues in question and trial of the case; and (3) whether discovery is complete and whether a trial date has been set." *Xerox Corp. v. 3Com Corp.*, 69 F. Supp. 2d 404, 406 (W.D.N.Y. 1999). *See also Depomed Inc. v. Purdue Pharma L.P.*, No. 13-

571 (JAP), 2014 U.S. Dist. LEXIS 102109 (D.N.J. July 25, 2014).[3]

Because this is an unusual case, with the choice presented to the Court not being whether to proceed with the '427 claims or not, but rather whether to stay the case entirely, or to allow for certain disclosure and discovery in order to minimize the prejudice to Actavis from a stay, the second and third parts of the standard test do not apply here. Rather, the real issue is what steps can be taken to minimize the impact on Actavis of a proposed complete stay that is being requested by Impax, when that stay is based solely on Impax's "hope" that it will reverse the PTO's rejections of its amended claims through a potentially lengthy appeals process.

ARGUMENT

A. ACTAVIS WOULD BE UNDULY PREJUDICED AND AT A CLEAR TACTICAL DISADVANTAGE RELATIVE TO IMPAX IF IMPAX's COMPLETE STAY IS GRANTED.

1. Impax's Proposed Stay Is Likely To Be of Long Duration

One aspect of the unfair prejudice from Impax's proposed complete stay arises because any stay of the '427 claims is likely to be lengthy. Impax states in its brief that it is "hopeful that the PTO could issue a decision shortly after oral argument [on June 1, 2016] – and thus the stay would be brief." D.I. 43-1 at 1 (also acknowledging that "there is no definitive timetable for a final decision"). But Impax ignores that the three examiners who have considered Impax's proposed amended claims for the '427 patent have unanimously rejected them as invalid.

[3] Generally speaking, in most of the cases cited by Impax in its brief, the party seeking the stay of a case pending the outcome of an ongoing reexamination is a patent defendant hoping to avoid the expense of discovery and trial. The principal exception to that rule is in Hatch-Waxman cases, where the patent owners whose patents are facing reexamination have an incentive to delay litigation in order to either confirm the validity of their patents and/or obtain potentially favorable amendments, or delay the time at which a prevailing ANDA filer may be able to obtain FDA approval of the ANDA and launch the competing generic product. *See, e.g., CIMA Labs Inc. v. Actavis Group HF*, Civ. Nos. 07-893 (DRD), 06-1970 (DRD), 06-1999 (DRD), 2007 WL 1672229 (D.N.J. June 7, 2007); *Genzyme Corp. v. Cobreck, Pharms., Inc.*, No. 10-cv-00112, 2011 WL 686807 (N.D. Ill. Feb. 17, 2011).

Indeed, Impax has given this Court *no* evidence and *no* argument as to why the PTAB or even the Federal Circuit is likely to overturn the PTO's rejections.

In fact, statistics indicate that the PTAB oral argument that Impax has pinned its hopes on will likely result in an affirmance of the PTO's rejection of Impax's proposed amended '427 claims. Statistics show that 62% of PTAB appeals from the Central Reexamination Unit in FY2014 resulted in a disposition of affirmance.[4]

It is hard to believe that, if the PTAB affirms the PTO's current rejection of Impax's proposed amended claims, then Impax will simply decide to give up and dismiss its claims. More likely, it will seek rehearing by the PTAB or appeal to the Federal Circuit, and so the stay would then continue. Once at the Federal Circuit, there is additional delay. Statistics indicated that in FY2015 there was an 11-month wait in the median time from disposition to termination of cases after hearing or submission of Patent and Trademark cases at the U.S. Court of Appeals for the Federal Circuit.[5]

Other evidence also points to a likely lengthy delay during appeals to the PTAB and then the Federal Circuit. As one analysis put it in a report copyrighted 2012: "The appeal process can easily take more than four years (through the Federal Circuit), even though the PTO is trying to address the various delays."[6] This does not even take into account any time required for any

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[4] USPTO, *Receipts and Disposition by Technology Center*, http://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/ptab-statistics-receipts-and-dispositions (last visited April 25, 2016) (for the Central Reexamination Unit, FY 2014 Cumulative Dispositions: 243 affirmed / 391 cases = 62%). Mueller Decl., Ex. 2.

[5] United States Court of Appeals for the Federal Circuit, Median Disposition Time for Cases Terminated After Hearing or Submission Chart 2006-2015, http://www.cafc.uscourts.gov/the-court/statistics (last visited April 25, 2016). Mueller Decl., Ex. 3.

[6] Sterne, Kessler, Goldstein & Fox, P.L.L.C., *Terms and Concepts Pendency*, http://ptolitigationcenter.com/2009/09/pendency/# (copyrighted 2012; last visited April 25, 2016), at p. 3. Exhibit 4 to the Declaration of Kenneth Mueller, Esq. ("Mueller Decl.")

potential remand by the PTAB or the Federal Circuit for additional consideration of issues by the PTO itself.

In short, unless Impax beats the odds and obtains a complete and quick victory and allowance of its amended claims in the PTAB, there is a high likelihood that Impax's stay with respect to the '427 patent would remain in effect for years. And in turn, that would mean that the 30-month stay would remain in place as well during the '427 stay, thus prejudicing the possibility of Actavis obtaining an earlier resolution of this case. And if Impax does obtain allowance of its proposed amended claims, there would be the further delay as the '427 case is litigated to final completion on a separate, later track.

Impax has cited cases standing for the proposition that "delay inherent in the reexamination process is itself insufficient to establish prejudice." D.I. 43-1 at 7.[7] But that argument completely misses the point. Here, the case will proceed in a timely fashion with respect to the other patents-in-suit. Under Impax's proposal, no progress at all would be made with respect to the '427 case during the appeals process, even though progress could be made in the meantime to alleviate the impact of the delay. Under Actavis's proposal, at least some progress would be made on the '427 patent, thus alleviating the prejudice caused by any reexamination-induced delay.

[7] Impax's cases, while not on point, are also counterbalanced by cases going the other way and denying a stay because of the prejudice resulting from the delay itself. *See, e.g.*, *Skyline Steel v. Pilepro LLC.*, 2015 WL 556545 *1 (S.D.N.Y. Feb. 9, 2015) (stating "Courts in this Circuit have found that the prejudice resulting from the potential for delay justifies denying a request for a stay pending parallel PTO proceedings, and there is no reason to reach a different conclusion here."); *citing Capital Bridge Co., Ltd. v. IVL Technologies Ltd.*, 2006 WL 2585529, at *2, n1 (S.D.N.Y. Aug. 30, 2006) (denying the plaintiff's motion for a stay in light of pending PTO proceedings and noting that "the uncertain length of the delay contemplated by Plaintiff's request alone" justifies refusing to grant a stay).

2. The Equities Weigh Against Impax

Another reason to deny Impax's request for a complete stay, and instead to allow certain activities to continue in the meantime, is that in this case, the equities clearly do not lie with Impax, for multiple reasons.

First, when Impax filed suit against Actavis on the '427 patent, Impax already knew it had abandoned the issued '427 claims, and that those claims could not be enforced. Its proposed amended '427 claims also had already been rejected by the PTO in the reexamination. Rather than wait to bring suit on the '427 patent if any amended claims were affirmed on appeal, Impax chose instead to sue on claims that it knew could not be enforced and were effectively moot from the start.

Even so, having filed its complaint, Impax did ***not*** promptly move for a stay of the '427 patent early in this case. Instead, there was some preliminary discussion about what to do with the '427 claims, but no resolution was reached and in the end the parties negotiated and agreed to a case schedule that was premised on completing litigation of *all* the patents-in-suit in a time frame that would allow completion of the case before the expiration of the 30-month stay. *See* D.I. 33. Based on that negotiated schedule, Actavis made its invalidity and non-infringement disclosures on the '427 patent, and the other patents as well.

Only as the time approached for Impax to disclose its infringement and validity contentions, did it decide to move for a stay. *See, e.g.*, D.I. 43-1 at 1 (stating that one of the triggering reasons why it moved for a stay on April 19, 2016, was "it is now evident that the reexamination proceeding will not be completed before at least Impax's preliminary contentions are due to be served."); *id.* at 5 (noting that Impax's contentions are due June 3, 2016). Actavis proposed the possibility of continuing with discovery rather than staying the '427 case in its entirety, but Impax declined. The result is that that if Impax's complete stay is granted, Actavis

will have received ***no*** disclosure from Impax of the basis for its infringement contentions, until potentially years from now.

Nor is such an imbalance in disclosures justified by a high likelihood that Impax will win its appeal and gain allowance of its amended claims in the near future. As noted above, Impax provides no evidence or argument that it is likely to succeed on its appeal, much less in a short time period.

3. A Partial Stay That Requires Impax to Disclose its Contentions Under the Local Rules and Allows For Fact Discovery Pertaining to the '427 Patent Would Reduce the Prejudice of the Stay on Impax, and Would Be an Efficient Use of Time and Resources While the Appeals Process Plays Out.

Actavis agrees that at the present time (before there has even been a hearing on Impax's appeal to the PTAB) there is some logic in deferring certain activities – including Markman proceedings and expert reports for the '427 patent – during the '427 appeals process. Actavis believes that the likelihood is that the invalidity of the proposed amended '427 claims will be ***affirmed*** on appeal by the PTAB. But because Impax will likely appeal to the Federal Circuit if that happens, there would continue to be at least a possibility that amended claims could be allowed, and it could be some time before the final outcome, and perhaps the final language of any '427 claims that emerge from appeal, will be known. But because Actavis would be unduly prejudiced by the Impax's *complete* stay of all activities, such a stay should not be ordered. Rather, any order should provide for two ways in which the prejudice could be alleviated even while the reexamination appeal is pending:

First, Impax should be required to complete and serve its Local Patent Rule 3.1, 3.4A & 3.6 contentions with respect to the '427 claims as issued. Impax should be able to explain in detail the basis for is infringement claims, which it has not done so to date. For example, Impax has not yet disclosed *any* factual basis for the proposition that Actavis's ANDA products

allegedly meet the detailed in vitro dissolution rate claims set forth in Claim 1 and incorporated into every claim at issue. The relevant claim language – set forth above in the Background Facts – requires proof of (i) each accused product's *in vitro* dissolution rates for levodopa over different time periods for both an immediate release component and a controlled release component of the claimed drug formulation, plus (ii) the time for formation of an initial peak of *in vivo* levodopa concentration. This claim language thus requires factual support that presumably Impax has in its possession – since it accused Actavis of infringement – but has not yet disclosed. Actavis is directly prejudiced by Impax's withholding of its detailed infringement disclosures on this and other original claim limitations that also carry over into the proposed amended claims, when it obviously could make these disclosures in time with the agreed-upon date in the current scheduling order.

If Impax is not required to make these disclosures, it will have an unfair advantage if and when new claims are allowed as a result of the appeal process. Impax already has a copy of Actavis's ANDA filing and thus knows in great detail the nature, features and performance of the accused ANDA products. There is no dispute that there is going to be some delay before Impax will hear of the results of its appeal to the PTAB, and for the reasons already stated, there is likely to be even longer delays as Impax appeals to the Federal Circuit. Precluding Actavis from receiving Impax's infringement and invalidity contentions, gives Impax – in effect – a potentially multi-year "extension" on analyzing the evidence and formulating its infringement theories for the '427 patent, without having to disclose that evidence and those theories to Actavis until after a final reexamination certificate issued and the stay is lifted.

Second, as already discussed above, Actavis should be allowed to proceed with discovery concerning the facts relating to the '427 patent. As the Court is aware, the passage of time can

make fact discovery more difficult, as memories fade or documents are lost. And here, fact discovery relating to the '427 patent overlaps with the fact discovery needed for the other five patents-in-suit. Such discovery would clearly be useful if Impax does overturn the present rejection of its proposed amended claims. Indeed, that some fact discovery had already been taken if and when the case revives would reduce the time required for any post-stay litigation over the '427 patent.

CONCLUSION

For all the reasons stated above, Impax's motion for a complete stay of the case with respect to the '427 patent pending completion of the reexamination of the '427 patent should be denied. Actavis asks the Court to require Impax to provide its Local Patent Rule disclosures on June 3, 2016 as previously agreed and set forth in the Court's scheduling order. Actavis further asks the Court to allow Actavis to take fact discovery from Impax concerning the '427 patent, as described above.

Respectfully submitted,

s/ Liza M. Walsh

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APPENDIX A

Claim 1 of the '427 Patent as issued	**Amended Claim 1 of the '427 Patent as proposed by Impax (12/29/2014)**
1. A pharmaceutical dosage form having an immediate release component and a controlled release component comprising: a) an immediate release component comprising a ratio of Carbidopa to Levodopa of from about 1: 1 to about 1: 50 such that the in vitro dissolution rate of the immediate release component according to measurements under the USP paddle method of 50 rpm in 900 ml aqueous buffer at pH 4 at 3 7° C. is from about 10% to about 99% Levodopa released after 15 minutes and from about 60% to about 99% after 1 hour; and b) a controlled release component comprising a ratio of Carbidopa to Levodopa of from about 1: 1 to about 1: 50 such that the in vitro dissolution rate of the controlled release component according to measurements under the USP paddle method of 50 rpm in 900 ml aqueous buffer at pH 4 at 3 7° C. is from about 10% to about 60% Levodopa released after 1 hour; from about 20% to about 80% Levodopa eased after 2 hours; and from about 30% to about 99% Levodopa released after about 6 hours, the in vitro release rate chosen such that the initial peak plasma level of Levodopa obtained in vivo occurs between 0.1 and 6 hours after administration of the dosage form to a patient.	**1.** A pharmaceutical dosage form having an immediate release component and a controlled release component comprising: a) an immediate release component comprising a ratio of Carbidopa to Levodopa of from about 1: 1 to about 1 :50 such that the in vitro dissolution rate of the immediate release component according to measurements under the USP paddle method of 50 rpm in 900 ml aqueous buffer at pH 4 at 37° C[.] is from about 10% to about 99% Levodopa released after 15 minutes and from about 60% to about 99% after 1 hour; and b) a controlled release component comprising a ratio of Carbidopa to Levodopa of from about 1: 1 to about 1 :50 such that the in vitro dissolution rate of the controlled release component according to measurements under the USP paddle method of 50 rpm in 900 ml aqueous buffer at pH 4 at 37° C[.] is from about 10% to about 60% Levodopa released after 1 hour; from about 20% to about 80% Levodopa released after 2 hours; and from about 30% to about 99% Levodopa released after about 6 hours, the in vitro release rate chosen such that the initial peak plasma level of Levodopa obtained in vivo occurs between 0.1 and 6 hours after administration of the dosage form to a patient <u>wherein the controlled release component comprises controlled release particles or granules; and wherein the Carbidopa and Levodopa are combined in the controlled release particles or granules.</u>